

**510(k) Summary**

JAN 26 2011

**Micrus Endovascular Corporation  
Micrus® Ascent® Occlusion Balloon Catheter**

This 510(k) Summary for the Micrus Ascent Occlusion Balloon Catheter is submitted in accordance with the requirements of 21 C.F.R. § 807.92.

**GENERAL INFORMATION**

**Manufacturer:** Micrus Endovascular Corporation  
821 Fox Lane  
San Jose, CA 95131  
Phone: 408-433-1400,  
Est. Registration No. 2954740

**Contact Person:** Patrick Lee  
Manager, Regulatory Affairs  
Phone: (408) 433-1428  
[plee@micruscorp.com](mailto:plee@micruscorp.com)

**Date Prepared:** December 21, 2010

**DEVICE CLASSIFICATION**

**Classification:** Class II  
**Trade Names:** Micrus® Ascent® Occlusion Balloon Catheter  
**Generic/Common Name:** catheter, intravascular occluding, temporary  
(21CFR § 870.4450)

**PREDICATE DEVICES**

- 510(k) no. K091504, Micrus Ascent and Summit Occlusion Balloon Catheter, June 19, 2009

**INDICATIONS FOR USE**

The Micrus Ascent Occlusion Balloon Catheters are intended for use in the blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired and offers a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The Micrus Ascent Occlusion Balloon Catheters are also intended to assist in the delivery of diagnostic agents such as contrast media, and therapeutic agents such as occlusion coils, into the peripheral and neuro vasculature.

## **DEVICE DESCRIPTION**

The Micrus Ascent Occlusion Balloon Catheters are coaxial dual lumen balloon catheters comprised of an inner guidewire lumen and a separate outer lumen to inflate and deflate the balloon. The balloon catheter is designed for use over any .014" or smaller guidewire. The balloon can be inflated and deflated independently of guidewire position. The balloon is equipped with a vent hole for easy preparation and removal of air from the balloon, and with two radiopaque markers for balloon positioning. Certain balloon catheter sizes may have a third radiopaque marker band 3 cm proximal to the tip to facilitate fluoroscopic visualization.

The modification made to the predicate device included: (1) an extended coating to cover the balloon body, (2) a change to a tighter tolerance on the PTFE inner liner, (3) changing the vent hole size from a circular shape to a larger rectangular shape, (4) modifying a manufacturing step to accommodate a better fusing of the proximal sections, (5) revised IFU to clarify the instructions

## **SUBSTANTIAL EQUIVALENCE**

The modification to the device has not altered the fundamental technology of the predicate devices. The Micrus Ascent Occlusion Balloon Catheters are substantially equivalent to the predicate device in terms of intended use, design, specifications, methods and materials in construction, packaging, and sterilization and materials.

The tests that were conducted to establish substantial equivalence includes:

- *in-vitro* tests, verifying that the modified device met acceptance in terms of:
  - balloon cycling and fatigue
  - balloon burst diameter and volume changes
  - coating integrity of the balloon
  - pressure at the design diameter of the balloon
  - inflation and deflation functions
  - trackability of the device in a simulated tortuous anatomy
  - the preparation method is adequate and acceptable
- *in-vivo* study – 1 porcine model with 7 devices, demonstrating that
  - the preparation method is adequate and acceptable
  - the device deployed effectively and as expected in a animal model
  - the trackability of the device met physicians' acceptance
  - the balloon remained stable in position after placement

## **CONCLUSION**

As described in this 510(k) Summary, Micrus Endovascular Corporation considers the modified Micrus Ascent Occlusion Balloon Catheters to be as safe, as effective, and performs as well as or better than the legally marketed device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Micrus Endovascular Corp.  
c/o Mr. Patrick Lee  
Manager of Regulatory Affairs  
821 Fox Lane  
San Jose, CA 95131

JAN 26 2011

Re: K103780

Trade/Device Name: Micrus Ascent Occlusion Balloon Catheter  
Regulation Number: 21 CFR 870.4450  
Regulation Name: Vascular Clamp (Catheter, Intravascular Occluding, Temporary)  
Regulatory Class: Class II  
Product Code: MJN  
Dated: December 21, 2010  
Received: December 27, 2010

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K103780

Device Name: Micrus Ascent Occlusion Balloon Catheter

### Indications For Use:

The Micrus Ascent Occlusion Balloon Catheters are intended for use in the blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired and offers a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The Micrus Ascent Occlusion Balloon Catheters are also intended to assist in the delivery of diagnostic agents such as contrast media, and therapeutic agents such as occlusion coils, into the peripheral and neuro vasculature.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

510(k) Number K103780

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